



# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE CASE NO. 02-896-A

In Re Applic	cation of:	)	
	Gould, et al	)	
		)	Examiner:
Serial No.:	10/678,927	)	
	,	)	Group Art Unit: 1614
Filed:	<b>October 3, 2003</b>	)	
		)	
Title:	Method for Treating	)	
	Patients with Massive	)	
	Blood Loss	)	

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### TRANSMITTAL LETTER

In regard to the above identified application:

- 1. We are transmitting herewith the attached:
- 2. a. Transmittal Letter;
  - b. Form PTO 1449 and 52 cited references;
  - c. Postcard.
- 3. No Fee is required.
- 4. Please charge any additional fees or credit overpayment to Deposit Account No.13-2490.

Respectfully submitted,

McDONNELL BOEHNEN HULBERA & BERGHOFF

Patrick G. Gattari Reg. No. 39,682

McDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE CHICAGO, ILLINOIS 60606

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the papers, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313 on this 440 day of WWW 2004.

(Rev. 2-32)	
FEB 0 9	2004 22 Mary

**FORM PTO-1449** 

# U.S. Department of Commerce

Patent	and	Trademark	Office
			•

INFORMATIO	NC	ISCL	ost	JRE
STATEMENT	BY	APPL	.ICA	NT

Use several sheets if necessary)

Atty.	Docket	No.
•		

02-896-A

Serial No.

10/678,927

# Applicant:

Gould, et al

Filing Date:

Group:

October 3, 2003

# 1614

#### **U.S. PATENT DOCUMENTS**

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1	5,691,453	11/25/97	Wirtz, et al			
	2	5,084,558	01/28/92	Rausch, et al			
	3	5,890,852	11/28/98	Rausch, et al			
	4	5,955,581	09/21/98	Rausch, et al			· ·
	5	5,691,452	11/25/97	Gawryl, et al			
	6	6,150,507	11/21/00	Houtchens, et al			
-	7	5,895,810	04/20/99	Light, et al			
	8	6,271,351	08/07/01	Gawryl, et al			
	9	6,288,027	09/11/01	Gawryl, et al			
	10	4,826,811	05/23/89	Sehgal, et al			
	11	5,464,814	11/07/95	Sehgal, et al			
	12	6,498,141	12/24/02	DeWoskin, et al			
	13	2002/0065211	05/30/02	Jacobs, Jr., et al			

EXAMINER	DATE CONSIDERED

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.	Serial No.
INFORMATION DISC STATEMENT BY API	ELOSURE	02-896-A	10/678,927
FEB 0 9 2004 &	Applicant:		
· PADEMANTA	Gould, et al		
BADEMAN		Filing Date:	Group:
		October 3, 2003	# 1614

#### **FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclass	Trans	lation
						Yes	No
-							

# OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

14	Gould, S.A., et al., The Life-Sustaining Capacity of Human Polymerized Hemoglobin when Red Cells Might Be Unavailable, Journal of the American College of Surgeons, 195 (4): 445-455 (October, 2002).
15	Carson, J.L., et al., Mortality and morbidity in patients with very low postoperative Hb levels who decline blood transfusion, Transfusion, 42: 812-818 (July, 2002).
16	Moore, F.A., et al., Trauma Resuscitation, ACS Surgery-Principles & Practice, 31-61 (2002).
17	American College of Surgeons Committee on Trauma. Advanced Trauma Life Support Program for Physicians 1997 Instructional Manual, 6 <sup>th</sup> , ed. Chicago: American College of Surgeons; 98-117 (1997).
18	Farion, K.J., et al., Changes in Red Cell Transfusion Practice among Adult Trauma Victims, J. Trauma, 44(4):583-587 (1998).
19	Baker, J.B., et al., Type and Crossmatch of the Trauma Patient, J. Trauma, 50(5):878-881(May, 2001).
20	DeFoe, G.R., et al., Lowest Hematocrit on Bypass and Adverse Outcomes Associated with Coronary Artery Bypass Grafting, Ann Thorac Surg., 71:769-776 (2001).

DATE CONSIDERED

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.	Serial No.
INFORMATION DIS STATEMENT BY A	CLOSURE	02-896-A	10/678,927
(Use several sheets i	f necessary)		
OIPE		Applicant:	·
FEB 0 9 2004 15		Gould, et al	
∥ \ ≨#		Filing Date:	Group:
TRADEMINIST.		October 3, 2003	# 1614

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

21	Wu, W.C., et al., Blood Transfusion in Elderly Patients with Acute Myocardial Infarction, New England
 22	Journal of Medicine, 345(17):1230-1236 (October, 2001).  Practice Guidelines for Blood Component Therapy: A report by the American Society of Anesthesiologists Task Force on Blood Component Therapy, Anesthesiology 84(3):732-747 (March, 1996).
23	Consensus Conference. Perioperative Red Blood Cell Transfusion, JAMA 260(18): 2700-2703 (November, 1988)
24	Gould, S.A., et al., Fluosol DA-20 As A Red Cell Substitute in Acute Anemia, New England Journal of Medicine, 314(26):1653-1656 (June, 1986).
25	Spence, R.K., et al., Fluosol DA-20 in the treatment of severe anemia: Randomized, controlled study of 46 patients, Critical Care Medicine, 18(11):1227-1230 (November, 1990).
26	Spence, R.K., et al., Is Hemoglobin Level Alone a Reliable Predictor of Outcome in the Severely Anemic Patient? The American Surgeon, 58(2):92-95 (1992).
27	Carson, J.L, et al., Severity of Anaemia and Operative Mortality and Morbidity, Lancet 1(8588):727-729 (April, 1988).
28	Carson, J.L., et al., Effect of anaemia and cardiovascular disease on surgical mortality and morbidity, Lancet, 348(9034):1055-1060 (October, 1996).
29	Viele, M.K., et al., What can we learn about the need for transfusion from patients who refuse blood? The experience with Jehovah's Witnesses, Transfusion 34(5):396-401 (1994).
30	Sehgal L.R., et al., Polymerized pyridoxylated hemoglobin: A red cell substitute with normal oxygen capacity, Surgery 95:433-438 (1984).
31	Amberson, W.R., et al., Clinical Experience with Hemoglobin-Saline Solutions, J. Applied Physiology, 1(7):469-489 (January, 1949).
32	Brandt, J.L., et al., The Effects of Hemoglobin Solutions on Renal Functions in Man, Blood, 6:1152-1158 (1951).
33	Miller, J.H., et al., The Effect of Hemoglobin on Renal Function in The Human, Journal of Clinical Investigation, 30:1033-1040 (July, 1951).

EXAMINER	DATE CONSIDERED

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.	Serial No.
(Nev. 2-32)	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	02-896-A	10/678,927
	(Use several sheets if necessary)		
ON PETO		Applicant:	
CER U 9 LUO.		Gould, et al	
THE THAT CHAPTER		Filing Date:	Group:
TA TRADENA		October 3, 2003	# 1614

34	Savitsky, J.P., et al., A clinical trial of stroma-free hemoglobin, Clinical Phamacology Journal, 23(1):73-80
]	(January, 1978).
35	Carmichael, F.J., et al., A phase I study of oxidized raffinose cross-linked human hemoglobin, Crit Care Med,
	28(7):2283-2292 (2000).
36	Kasper, S.M., et al., Effects of a Hemoglobin-Based Oxygen Carrier (HBOC-201) on Hemodynamics and
30	Oxygen Transport in Patients Undergoing Preoperative Hemodiulution for Elective Abdominal Aortic Surgery,
	Anesth Analg, 83:921-927 (1996).
37	LaMuraglia, G.M., et al., The reduction of the allogenic transfusion requirement in aortic surgery with a
37	hemoglobin-based solution, J. Vascular Surgery, 31(2):299-308 (February, 2000).
	Sloan, E.P., et al., Diaspirin Cross-Linked Hemoglobin (DCLHb) in the Treatment of Severe Traumatic
38	
Hemorrhagic Shock, JAMA 282:1857-1864 (November, 1999).	
39	Gould, S.A., et al., Clinical Utility of Human Polymerized Hemoglobin as a Blood Substitute after Acute
	Ttrauma and Urgent Surgery, J. Trauma 43(2):325-332 (August, 1997).
40	Gould, S.A., et al., The First Randomized Trial of Human Polymerized Hemoglobin as a Blood Substitute in
	Acute Trauma and Emergent Surgery, J Am Coll Surg 187(2):113-122 (August, 1998).
41	Vengelen-Tyler, V., American Association of Blood Banks Technical Manual. 13th ed., Bethesda (MD):
	American Association of Blood Banks, p. 389-396 (1999).
42	Huston, P., et al., Withholding Proven Treatment in Clinical Research, New England Journal of Medicine
	345(12):912-914 (September, 2001).
43	Emanuel, E.J., et al., The Ethics of Placebo-Controlled Trials- A Middle Ground, New England Journal of
43	Medicine, 345(12):915-914 (September, 2001).
	Carson, J.L, et al., Mortality and morbidity in patients with very low blood counts who decline blood
44	transfusion, Transfusion, 42:812-818 (July, 2002).
45	Reiner, A.P., Massive Transfusion, Perioperative Transfusion Medicine, p.351-364 (1998).
46	Weiskopf, R.B., et al., Human Cardiovascular and Metabolic Response to Acute, Severe Isovolemic anemia,
	JAMA 279(3): 217-221 (January, 1998).

EXAMINER	DATE CONSIDERED

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.	Serial No.
INFORMATION I STATEMENT BY	DISCLOSURE	02-896-A	10/678,927
(Use several sheet	ts if necessary)		
OPE		Applicant:	
n a mak is		Gould, et al	
FEB US AND		Filing Date:	Group:
THE THROUGH THE STATE OF THE ST		October 3, 2003	# 1614

47	Wilkerson, D.K., et al., Limits of cardiac compensation in anemic baboons, Surgery, 103(6):665-670 (1988).
48	Levy, P.S., et al., Oxygen Extraction Ratio: A Valid Indicator of Transfusion Need in a Limited Coronary Vascular Reserve? J. Trauma 32(6):769-774 (June, 1992).
49	Schwartz, J.P., et al., The Influence of Coronary Stenosis On Transfusion Need., Cardiothoracic Surgery, Surgical Forum XLIV:226-228 (1993).
50	Moss, G.S., et al., Transport of Oxygen and Carbon Dioxide by Hemoglobin-Saline Solution in the Red Cell-Free Primate, Surg. Gynecol Obstet, 142:357-362 (March, 1976).
51	Frantantoni, J.C., <i>Points to consider on efficiacy evaluation of hemoglobin and perfluorocarbon based oxygen carriers</i> , Transfusion 34(8):712-713 (1994).
52	Frantantoni, J.C., <i>Red Cell Substitutes: Evolution of Approaches for Demonstrating Efficacy</i> , Blood-substitutes – Present and Future Perspectives, Elsevier Science S.A., p. 33-39 (1998).

DATE CONSIDERED